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ORIGINAL ARTICLE

Pascal laser versus conventional laser for treatment of diabetic retinopathy

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KEYWORDS

Pascal laser;
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Abstract *Purpose:* To compare the safety and efficacy of Pascal laser photocoagulation in comparison with the conventional laser photocoagulation in the treatment of diabetic retinopathy.
Patients and methods: A prospective randomized case series study was done on 120 procedures done in 120 patients divided into two main groups, group A, patients undergoing focal or modified grid macular laser and group B, patients undergoing panretinal photocoagulation (PRP). Each of the two groups were subdivided into two subgroups randomly in the first we used conventional laser photocoagulation (groups A1 and B1) and in the other we used Pascal laser photocoagulation (groups A2 and B2).
Results: Procedures in groups A1,2 and in groups B1,2 had successful outcomes. Significantly higher powers were required with the Pascal (groups A2 and B2) than with conventional laser (groups A1 and B1) ($p < 0.001$) in eyes that underwent PRP and focal/modified grid macular treatment with both systems. No adverse events were noted in all groups.
Conclusion: The Pascal photocoagulator is safe, rapid, effective, with rapid learning and had short exposure time. Although the shorter pulse duration of the Pascal necessitates the use of a higher power, it is not associated with adverse effects.

1. Introduction

Laser photocoagulation remains the second-most common eye procedure after cataract extraction, and yet little has changed in laser design over the last 35 years until recently. There are different colours, different laser sources and connecting cables, but otherwise we were still tied to the same single spot delivery system coupled to a slit lamp controlled by a joy stick. Conventional photocoagulation using a single application of laser energy per shot is usually delivered as a 100–200 ms duration burn. This gets difficult for the patients and the treating doctors and takes a long time especially in PRP (Roider et al., 2000).

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The PASCAL (Pattern Scan Laser) (Optimedica Corp., Santa Clara, CA, USA), which received United States Food and Drug Administration (FDA) clearance in 2005 uses a microprocessor-driven scanner that produces a variety of scalable patterns, viewable on a computer screen and selected by the physician. The laser allows the operator to apply multiple spots almost simultaneously, with a single foot pedal depression, multiple laser burns in a rapid predetermined sequence in the form of a pattern array produced by a scanner. To achieve this, pulse durations are reduced by nearly a log unit to about 10–20 ms compared with 100–200 ms with a traditional laser. This offers several potential advantages over conventional single spot laser, including increased uniformity and precision of spot placement and reduced pain (Muqit et al., 2009).

But as the type of damage mechanism to retinal pigment epithelium (RPE), other retinal layers and choroid depends on the duration of the applied laser pulse. At continuous wave (CW) to 10-ms exposure time, a pure thermal denaturation of tissue has been shown to be the primary retinal damage mechanism (Vogel and Lauterborn, 1988). While from microsecond to nanosecond exposure times, there is evidence that RPE damage is induced by intracellular microbubble formation around the strongly absorbent melanosomes inside the RPE cell (Brinkmann et al., 2000). The microbubble formation leads to a disintegration of the RPE cell structure and a disruption of the cell membrane. At subnanosecond exposures, other nonlinear damage mechanisms appear, such as shock-waves and laser-induced breakdown (Roegener et al., 2004).

Hence we did this prospective randomized case series study to compare the safety and effectiveness of Pascal laser photocoagulation in comparison with the conventional laser photocoagulation in cases of diabetic retinopathy (DR).

2. Patients and methods

A prospective randomized case series study was done after approval from medical and ethics committee. Informed written consents were taken from all patients for the specific procedure. Information was collected on age, sex, indication, pre- and post-laser procedure best corrected visual acuities (BCVA), need for subtenon's anaesthetic as well as outcome and complications of treatment and intra- and post-procedure pain sensation.

Inclusion criteria were patients with type 2 DR with need for laser either non-proliferative diabetic retinopathy (NPDR) with clinically significant macular oedema (CSME), focal or diffuse maculopathy and proliferative diabetic retinopathy (PDR).

Exclusion criteria were ischaemic maculopathy, previous laser or intravitrial injection, vitrectomy or associated retinal diseases as retinal vein occlusion.

Treatment parameters including use of a pattern or single spot, type of pattern, power, burn duration and number of burns per session were noted. The power, numbers of burns, spot size and burn duration were recorded in an effort to compare the settings needed with each system. Prior to starting treatment, the operator chose whether or not to do Pascal based on the random distribution by computer system after informed consents from all patients.

One hundred and twenty procedures of 120 patients divided into four groups: group A1, patients undergoing focal or modified grid macular laser photocoagulation for NPDR using conventional laser (The Novus Spectra which is a 532 nm green-light Diode Pumped Solid State (DPSS) Photocoagulator, Lumenis) with treatment durations: 10–3000 ms, spot size from 50 μm up to 500 μm and power from 50 mW up to 2500 mW.

Group B1, patients undergoing pan laser photocoagulation (PRP) for (PDR) using conventional (DPSS) laser photocoagulation, group A2, patients undergoing focal or modified grid macular laser photocoagulation for NPDR using Pascal laser photocoagulation and group B2, patients undergoing PRP for PDR using Pascal laser photocoagulation.

The Pascal (by OptiMedica, Silicon Valley, USA) is a 532 nm frequency-doubled (Nd:YAG) solid-state laser. It can deliver numerous patterns including squares, arcs, full and subset grids, the shapes and sizes of which are adjustable, in addition to single spots. For PRP, the 3×3, 4×4 and 5×5 arrays were most commonly used. Whether single spot or pattern array near-simultaneously setting was used with a single depression of the foot switch. All burns were placed one burn width apart.

For Pascal laser, subset grids and single spots were used for focal macular oedema. The full macular grid pattern was used for patients with diffuse macular oedema who had good fixation, but single spots were used for the rest. PRP group received 20 ms, 200 μm spot size in air using a contact lens with a spot-size magnification factor of 2× producing burns of approximately 350–400 μm on the retina. Macular photocoagulation was performed using 10 ms exposures and a spot size of 100 μm in air which produced a $\leqslant$100 μm burn on the macula because a contact lens with a spot-size magnification factor of 1× was utilised. Follow up was scheduled to be for 1 year clinically by BCVA, slit lamp biomicroscopy, indirect ophthalmoscopy, fundus photography and fundus fluorescein angiography (FFA).

Power needs to be varied in Pascal as with conventional lasers until the desired burn intensity is achieved according to variation in laser uptake due to contact lens curvature, refraction, eye curvature and tissue characteristics such as pigmentation and extent of retinal oedema and exudation, though efforts were made to avoid previous laser burns by adjusting the location of the arrays as necessary or changing the array pattern. Moderate intensity burns producing retinal blanching were used for PRP while macular burns were lighter. Treatment for groups A1 and A2 was deemed successful if the macula was dry and the oedema had resolved after 4 months, Groups B1 and B2 was deemed successful if, neovascularisation had regressed, and no further treatment was planned.

Data were analysed using SPSS (Statistical Package for Social Sciences V.17). Descriptive statistics were used to summarise data and explore groups. Visual acuities (VA) were converted from Snellen to log Mar to explore changes in vision pre- to post-laser. p value of <0.05 was considered significant and highly significant ($p < 0.001$).

3. Results

In the study, 120 procedures of 120 patients were performed, of whom 72 (60%) were male, and 48 (40%) were female with a mean age of 48.9 years (SD 9.3, range 41–86). VA did not differ significantly pre- to post-procedure ($p = 0.347$) in any

Table 1 Different pre- and post-laser parameters in all groups.

Parameters	Group A1 ME + CL	Group B1 PDR + CL	Group A2 ME + PL	Group B2 PDR + PL
No. of procedures	30	30	30	30
Prelaser VA log MAR, mean (SD)	0.30 (0.24)	0.31 (0.23)	0.30 (0.24)	0.6 (0.61)
Snellen equivalent	6/12	6/12	6/12	6/24
Post-laser VA log MAR, mean (SD)	0.22 (0.24)	0.30 (0.27)	0.30 (0.24)	0.53 (0.61)
Snellen equivalent	6/9	6/12	6/12	6/18
Power (mW), mean (SD)	100 (20.5)	215 (51.3)	332 (105.5)	410 (115.2)
No. of burns, mean (SD)	85 (76.6)	700 (201.1)	145 (92.2)	1090 (410.4)
Average follow-up (weeks), mean (SD)	10.8 (4.3)	10.8 (5.6)	9.32 (3.2)	9.0 (4.5)
Successful outcome	27/30	20/30	28/30	28/30

ME, macular oedema; CL, conventional laser; PL, Pascal laser.
log MAR, logarithm of the minimal angle of resolution; VA, visual acuity.

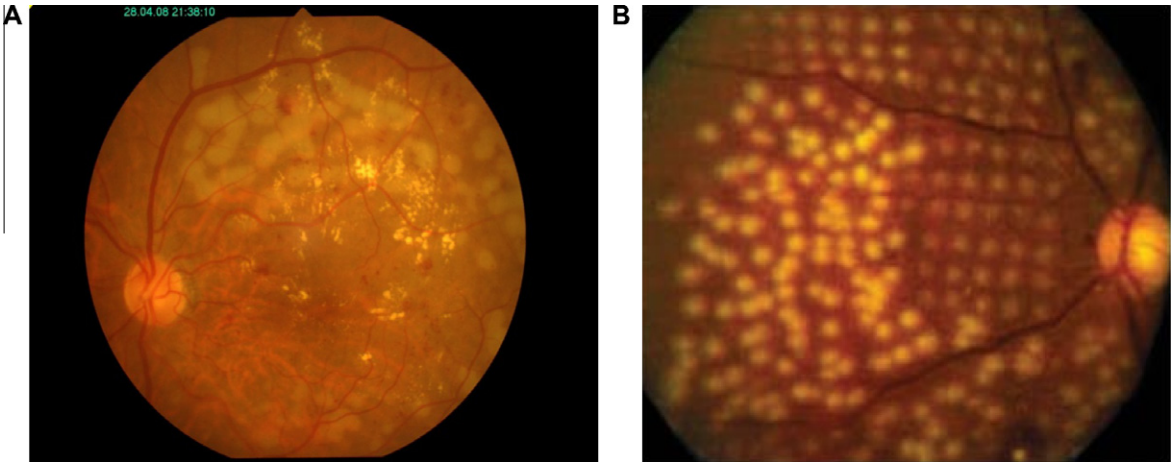

Figure 1 (A) Modified grid by conventional laser. (B) PRP for PDR with combined conventional laser and Pascal photocoagulation for comparison.

group. There were 30 (25%) procedures in group A1, 30 (25%) in group A2, 30 (25%) in group B1 and 30 (25%) in group B2. The average laser power, number of burns and mean follow-up period for the whole of groups are listed in Table 1.

The results were compared in terms of efficacy, power requirement, procedure length, pain and adverse events. The PASCAL burns were more precisely spaced and more uniform than the conventional single-spot burns (Fig. 2), higher power is required for the shorter time burns, and there was less subjective patient discomfort noted. On a scale of 0–5, with 5 being the most painful, standard laser was rated 2.72 by the patients and 0.61 for PASCAL.

Group A1 included 30 procedures with conventional laser, of which 17 (56.7%) was modified grid laser for diffuse diabetic macular oedema and 13 (43.3%) were focal treatments for focal diabetic macular oedema. Average power of 100 mW (SD 20.5, range 70–150), spot size 50–100 μm and burn duration of 50–100 ms. The mean number of burns was 85 (SD 76.6, range 15–276) (Fig. 1).

For group A2 included 30 procedures with Pascal laser 20 (66.7%) modified grid laser for diffuse diabetic macular oedema and 10 (33.3%) focal laser for focal macular oedema using the Pascal pattern and two using single spots.

Average power used in group A2 was 332 mW (SD 105.5, range 200–400), spot size 50–100 μm and burn duration of 10 ms. The mean number of burns was 145 (SD 92.2, range 120–250) (Figs. 1 and 2).

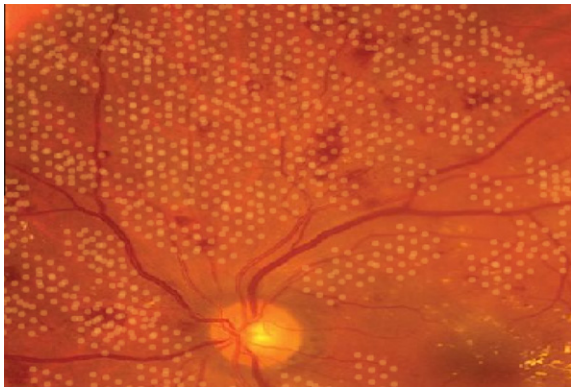

Figure 2 Combined PRP and modified grid by Pascal laser.

Significantly higher powers were used for Pascal (145 mW) than conventional laser (100 mW) ($p < 0.001$) treatment.

Following Pascal treatment, in 28 of the 30 procedures, the macula was dry, and no further laser was required. Two patients had residual CSME, of which one underwent further

laser, and one had intravitreal triamcinolone acetonide. Topical anaesthesia was sufficient in all groups.

For group B1 (30 procedures) with PRP by conventional laser for PDR the laser power needed using a 100 ms burn The average power was 215 mW (SD 53.1, range 150–400), and the mean number of burns was 700 (SD 201.1, range 300–1200).

For Pascal laser in group B2 (30 procedures) using a 20 ms burn mean power was 410 mW (SD 115.2, range 250–760), and the mean number of burns was 1090 (SD 410.4, range 440–2050) (Fig. 2).

The difference in powers used with the conventional and the Pascal lasers was highly significant ($p < 0.001$).

In our study success rate was nearly same in conventional A1 (27/30) and Pascal laser A2 (28/30) in cases of macular oedema.

This success rate was significantly higher ($p < 0.05$) with Pascal laser PRP group B2 (28/30) than conventional laser PRP group B1 (20/30) in PDR.

The Pascal was used for additional fill-in PRP in 10 of the 30 procedures of group B1 which had conventional laser photocoagulation, but this had not adequately controlled the neovascularisation. This group, therefore, allowed us to directly compare the laser power needed using a 100 ms burn for the conventional treatment with the laser power needed for the same eye during the Pascal episode using a 20 ms burn. The average power with the conventional photocoagulator for these 10 procedures was 225 mW (SD 51.2, range 160–400), and the mean number of burns was 725 (SD 221.2, range 300–1150). The Pascal parameters used for these 10 procedures were as follows: mean power was 400 mW (SD 110.2, range 240–750), and the mean number of burns was 1110 (SD 420.2, range 450–2000).

The difference in powers used with the conventional and the Pascal laser for these 10 patients was highly significant ($p < 0.001$), being 400 mW for Pascal compared with 225 mW for conventional laser.

Of these 10 procedures, 9 were successful with regression of neovascularisation at their latest follow-up visit. One eye needed further laser. Three patients had needed a subtenon's anaesthetic for their conventional laser session, but none of them required it for their Pascal procedure.

Of the 30 PRP procedures done exclusively with the Pascal, 14 (46.7%) were performed in a single session, and the rest were fractionated into two episodes. The mean number of burns given during single-session PRP was 1410 (SD 562.5, range 500–2000). None of the eyes with single-session PRP developed any complications, and regression of neovascularisation was noted in all, with no further treatment planned at their last follow-up visit.

No complications related to laser treatment were noted in any patient. No effects were observed on blood vessels if the array inadvertently involved a retinal area traversed by blood vessels. None of the patients experienced bleeding of either retinal or choroidal origin. No effects were observed due to the doctor being unable to avoid old laser burns in re-treatments.

4. Discussion

The interaction of laser radiation with biological tissue is of interest both for medical applications and for the establishment of laser safety standards. Laser treatments of retinal diseases are widely used in ophthalmology. During photocoagulation, the aim is to optimise thermally induced therapeutic effect but cause minimal retinal damage. Laser–tissue interaction is influenced by wavelength, spot size, power and exposure time. Retinal damage can be reduced by changing some of these parameters. Pascal technology utilises an exposure time of 10 ms for macular photocoagulation and 20 ms for PRP (Jain et al., 2008). Our study revealed that this brief exposure requires a higher power to achieve the desired therapeutic lesion.

In group A, the mean power used was significantly higher with the Pascal system (145 mW) than with the conventional system (100 mW) ($p < 0.001$). So higher power settings were needed with the Pascal system as compared with conventional photocoagulation.

Similarly 30 eyes with PRP in group B1 underwent photocoagulation with conventional laser and 10 needed additional Pascal PRP. There was a highly statistically significant difference in the mean power used between conventional laser (225 mW) and Pascal laser (400 mW) ($p < 0.001$).

However, these higher power levels required with the Pascal system did not result in any complications. This may be a reflection of the reduced laser energy per burn reaching the eye secondary to its shorter duration. Fluence is calculated as (power × time/area), and provided that spot size remains unchanged, with a burn duration of 20 ms the fluence is less than with a 100 ms burn when titrating to the same burn intensity because of reduced diffusion of heat (Bailey et al., 1999).

In our study success rate was significantly higher with Pascal laser PRP than conventional laser PRP in PDR and Pascal was successful in case of failed conventional laser (10 procedures). This can be explained by the easier way to apply Pascal laser to all retina in a shorter time and more comfortable for the patient and the doctor while in conventional laser some areas of the retina can be missed which increase failure rate. Also previous study showed that regression of neovascularisation is associated with greater areas of retinal ablation at the initial treatment session (Bailey et al., 1999). The cumulative total number of burns (Cordeiro et al., 1997).

This success rate was nearly same in conventional and Pascal laser in cases of macular oedema as it is easily accessible for application of laser.

There has been some concern that very short exposures may cause acoustic shock wave damage and haemorrhage. Some early argon laser studies showed a narrow safety margin between retinal burn and retinal haemorrhage for pulse durations less than 50 ms (Mainster et al., 1983; Obana et al., 1992). It has been since then shown that the point of change from thermomechanical cavitation-induced RPE damage to pure thermal RPE denaturation occurs at a 50 μs exposure time, a much shorter time than that employed by the Pascal system. At pulse durations longer than 10 ms, pure thermal denaturation of tissue is the primary retinal damage mechanism (Schuele et al., 2005; Sliney and Marshall, 1992). It is this thermal effect that produces therapeutically desirable retinal lesions (Mellerio, 1966). In histopathological study (Blumenkranz et al., 2006) using pulse durations of 20 ms, the threshold for a visible burn was 110–120 mW, while that for retinal haemorrhage was 600 mW, suggesting an adequate safety margin. Another recent study eyes has demonstrated that 20 ms pulse durations represent an optimal compromise between reduced collateral damage and sufficient width of the therapeutic window

(Blumenkranz et al., 2006). In our study we found good safety of Pascal laser as there were no intra or postoperative complications for 1 year follow up.

At a 5-μs laser pulse duration, microbubble formation has been shown to be the primary RPE damage mechanism. The point of change from thermomechanical microbubble induced RPE cell damage to pure thermal RPE denaturation is ~50-μs exposure time. At longer pulse durations, the primary damage mechanism is purely thermal.

The array method of multiple burn application allows for a larger area of retinal ablation in a shorter time. However, although single-session PRP may be possible with the Pascal system, its feasibility may be debatable due to concerns such as macular oedema and exudative retinal and choroidal detachments. In our patients, none who underwent single-session PRP had any complications, but the numbers were small to draw a conclusion. This was in agreement with Doft and Blankenship, who found that these effects occurred more in the first few weeks after single-session PRP, but the effects were transient, and no long-term difference between single and multiple session treatment groups was found (Doft and Blankenship, 1982).

In our patients, three patients who had previously undergone PRP using 100 ms burns required subtenon's anaesthetic for those procedures but were able to tolerate the Pascal procedure with only topical anaesthesia. A recent study has shown that shortening the exposure time to 20 ms is significantly less painful but equally effective as conventional parameters (ANSI, 2000).

5. Conclusions

From our study that we found that Pascal photocoagulator is safe, rapid, effective, with rapid learning curve and had short exposure time. Although the shorter pulse duration of the Pascal necessitates the use of a higher power, it is not associated with adverse effects.

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